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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,923

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EXAMINER

DESAI, ANAND U

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

07/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,923	Applicant(s) SHASTRI ET AL.	
	Examiner ANAND U. DESAI	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 26-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the amendment filed on April 29, 2008.
2. Claims 26-47 have been withdrawn previously.
3. Claims 1-25 are currently pending and are under examination.

Withdrawal of Rejections

4. The rejection of claims 1-6, 8-10, and 19 under 35 U.S.C. 102(e) as being anticipated by Simonnet et al. (U.S. Patent 6,379,683 B1) is withdrawn because the composition is not dispersed within a polymeric matrix.
5. The rejection of claims 1, 2, 5, 6, 8-11, 13-20, 22, and 24 under 35 U.S.C. 102(e) as being anticipated by Ketelson et al. (U.S. Patent Application Publication 2005/0002970 A1) is withdrawn because the composition is not dispersed within a polymeric matrix.
6. The rejection of claims 1, 2, 5, and 6 under 35 U.S.C. 102(b) as being anticipated by Oppenheim et al. (U.S. Patent 4,107,288) is withdrawn because the composition is not dispersed within a polymeric matrix.
7. The rejection of claims 1-25 under 35 U.S.C. 103(a) as being unpatentable over Simonnet et al. (U.S. Patent 6,379,683 B1) or Ketelson et al. (U.S. Patent Application Publication 2005/0002970 A1) or Oppenheim et al. (U.S. Patent 4,107,288) in view of either Perez, C. et al. (Journal of Controlled Release) and Li et al. (US 2002/0187104 A1) is withdrawn because the composition is not dispersed in a polymeric matrix.

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Pending Rejections

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. In claim 1 how is a structure in the micron size range a nanoparticle?

11. In claim 1 it is unclear how the nanoparticle comprises a structure? The nanoparticle is a structure. It is unclear if the particle a spherical structure or some other structure?

12. Claims 2-25 are rejected for depending on a rejected claim and failing to cure the indefiniteness of the claims.

Response to Remarks

13. Applicant's state that they are allowed to describe the invention in their own terms, and have made the meaning of those terms clear. Applicant's arguments filed April 29, 2008 have been fully considered but they are not persuasive. The use of the term nanoparticle to encompass a microparticle is repugnant to the art and would not clearly describe a nanoparticle. It is unclear how a nanoparticle would be a microparticle.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claim 10 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Response to Remarks

16. Applicants state the claimed product is not genetic material and that a chemical functional group comprises a structural description. Applicants state the Eli Lilly standard for genetic material is not applicable to claim 10. Applicant's arguments filed April 29, 2008 have been fully considered but they are not persuasive.

The term “derivates thereof” does not specifically define any of the chemical structures that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original).

Just as the claims at issue in *UC v. Lilly* defined the invention by the function of the claimed DNA (encoding insulin), the instant claims define the claimed products only by their functional properties (e.g. derivatives of chemical functional groups). The court held this sort of functional definition insufficient. “In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly such a formula is normally an adequate description of the claimed genus. The term, “derivates thereof” does not specifically define any of the chemical structures that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.” *UC v. Lilly*, at *24-*25, thus the above claims lack adequate written description, because the person having ordinary skill in the art would not distinguish the genus from others. The disclosure does not describe what the structural modifications for the chemical functional groups are that encompass the derivatives thereof.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1, 2, 10, 13, 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Pramanik, P. et al. ([Papers presented at the International Conference on Science and Technology of Nanostructured Materials], Puri, India, Jan. 4-8, 2001 (2001), 241-253. Editor(s): Rao, B. K. Nova Science Publishers, Inc.: Huntington, N. Y. ABSTRACT ONLY).

19. Pramanik, P. et al. disclose a metallo-organic route for the preparation of nanosized inorganic oxides and study of their chemical properties. Pramanik, P. et al. discuss the preparation of various nano-sized inorg. oxides through the thermolysis/flame pyrolysis of an metallo-organic complex based precursor solution. The precursor solution was constituted of the desired metal ions complexed with an organic chelating group and dispersed in a polymeric matrix. Spray-drying/rapid evaporation of the precursor solution produced the precursor powders which on calcination at appropriate temps. produced the nano-sized oxides. The various complexing agents used in the precursor solution as the ligands for complexation with the metal ions were organic amines [such as: diethanolamine (i.e., DEA) and triethanolamine (i.e., TEA)] and different organic acids (such as: oxalic, tartaric and citric acids). The organic amines/acids are useful complexing agents for the preparation of multi-component inorg. oxides specially where the constituent metal complexes have widely different solubilities. Aqueous solution of PVA (polyvinylalc.) or an aqueous solution mixture of sugar and PVA provided the

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polymeric matrix for the dispersion of the metallo-organic complexes. The process is versatile for the preparation of nanocryst. simple oxides (such as: ZrO₂, Al₂O₃, Cr₂O₃ etc.) and various other complex oxides (such as PZT, PLZT, PMN, PFN, SBN, ferroelec. tantalates, inorg. oxide superconductors etc.). The particle size of the resulting high purity powders ranged between 10 to 90 nm, their distribution were narrow and were obtained at a relative lower pyrolysis temps. than those reported in literature so far.

Conclusion

20. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

July 20, 2008

/Anand U Desai, Ph.D./

Patent Examiner, Art Unit 1656